

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION


OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

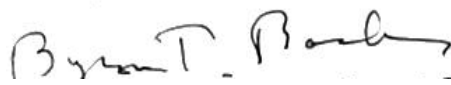
May 26, 2022

MEMORANDUM:

Subject: Acute Toxicity Review for EPA File Symbol: 2749-AER

Applicant: Aceto Life Sciences, L.L.C.
Product Name: AG35814 C 70 WP Insecticide
DP Barcode: D463788
Decision No.: 576685
Action Code: R301
PC Code(s): 099050 Acetamiprid (70%)

From: Odbert Triplett Toxicologist 
Chemistry, Inerts and Toxicology Assessment Branch (CITAB)
Registration Division (7505T)

Through: Byron T. Backus, Ph.D., Biologist 
Chemistry, Inerts and Toxicology Assessment Branch (CITAB)
Registration Division (7505T)

To: Marianne Lewis
Venus Eagle, RM 01
Invertebrate-Vertebrate Branch 3
Registration Division (7505T)

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Acetamiprid:.....	70.0%
Other Ingredients:	30.0%
Total: 100.0%	

ACTION REQUESTED: The Risk Manager requests a review of acute toxicity studies cited in support of AG35814 C 70 WP Insecticide, EPA File Symbol: 2749-AER.

BACKGROUND:

Aceto Life Sciences, L.L.C. has applied for registration of AG35814 C 70 WP Insecticide, EPA File Symbol: 2749-AER, claiming to be substantially similar to Assail 70WP, EPA Reg. No. 8033-23. Both products contain 70% Acetamiprid. The label indicates that it is "For Agricultural Use Only". The submission includes, label, data matrix, company letter and a Basic CSF dated June 20, 2021 with Inerts Approved for Food Use under 40 CFR 180.920, Pre-Harvest Application to Growing Crops.

The registrant is using the selective method of data support to satisfy the acute toxicity data requirements. The data matrix dated June 20, 2021 cites acute toxicity studies MRIDs 44651821-6 (used to satisfy the acute toxicity data requirements for 8033-23). A search of the OPP electronic databases shows that MRIDs 44651821-6 were submitted for registration of the cited product which was originally registered as 264-609, Assail brand Tristar 70 WP Insecticide (Bayer CropScience LP) then transferred to Nippon Soda Co., Ltd. March 15, 2002 to become Assail 70WP, EPA, Reg. No. 8033-23. The cited studies were reviewed and found acceptable in a 2002 Technical Review Branch (TRB) memo (Hashim, M.; TXR 5002772).

The Agency reviewed the data to assess the acute toxicity, irritation, and dermal sensitization potential of the proposed product (see Toxicity Profile under "Comments and Recommendations").

COMMENTS AND RECOMMENDATIONS:

1. After comparing the proposed CSF for 2749-AER with the CSF for 8033-23 (dated 02/07/2002, E-file 651930_4_CSf.pdf), it is concluded that although there are some compositional and/or percentage differences involving inerts, the two formulations are toxicologically similar and have the same acute toxicity profile with the exception of eye irritation potential. We recommend that 2749-AER be assigned to toxicity category III by this exposure route.
2. The MRIDs cited were used to satisfy the acute toxicity data requirements for 8033-23, and therefore can also be used to satisfy the acute toxicity data requirements for 2749-AER which would be assigned to toxicity category III for eye irritation.
3. The Basic CSF and any chemistry data or citations to chemistry data must also be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.
4. Based on similarity to 8033-23, the following is the acute toxicity profile for AG35814 C 70 WP Insecticide, EPA File Symbol: 2749-AER:

Acute oral toxicity	cited	III	MRID	44651821
Acute dermal toxicity	cited	III	MRID	44651822
Acute inhalation toxicity	cited	IV	MRID	44651823
Primary eye irritation	cited	III*	MRID	44651824
Primary dermal	cited	IV	MRID	44651825
Dermal sensitization	cited	negative	MRID	44651826

*Assigned to toxicity category III based on compositional differences involving inerts.

EPA Reg. No. / File Symbol: 2749-AER
PC Codes: 099050

Based on the acute toxicity profile as well as information from the proposed label and CSF, the following is the precautionary and first aid labeling, as obtained from the Label Review System:

Product ID: 2749-AER

Product Name: AG35814 C 70 WP Insecticide

Precautionary Statements:

Keep out of Reach of Children.

Signal Word: **CAUTION**

Poison Label: **None**

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation.

Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

The registrant has included the phrases "Harmful if inhaled. Avoid breathing vapors or spray mist" and "Keep out of reach of children and domestic animals" which are consistent with the last accepted (June 11, 2021) label of the cited product and are acceptable.

Personal Protective Equipment (PPE):

- Wear long-sleeved shirt and long pants,
- Socks and shoes,
- (waterproof or chemical-resistant) gloves

The PPE listed by the registrant are acceptable.

Additional labeling should include (but not necessarily be limited to) the following:

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations:

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.

- Do not give anything by mouth to an unconscious person.

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

The first-aid statements as proposed by the registrant are acceptable.

EPA encourages but does not require (see PR Notice 2001-1) registrants to include a company telephone number or toll-free hotline for emergency information in the first aid section. If a number is included, confusion can be avoided by specifying emergency vs non-emergency numbers. It should include a phrase or statement indicating the kinds of information the number should be used for and it may include hours of service. The following are examples of appropriate statements that may be included on the label:

- Have the product container or label with you when calling a poison control center or doctor or going for treatment.
- For medical emergencies, call the poison control center at 1-800-222-1222.
- For general information about this product, call 1-XXX-XXX-XXXX [may include hours of service], or contact the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 AM to 12 PM PST, or at <http://npic.orst.edu>.

The proposed label includes a telephone number and a statement to have the product container and label when calling to a poison control center or doctor, along with a contact phone number for emergency medical information. These statements are appropriate and acceptable.

5. We can accept the precautionary and first aid statements as proposed by the registrant for 2749-AER which are consistent with those of the cited label and with assignment to toxicity category III for eye exposure.